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From: Stralka, Daniel

Sent: Wed 1/15/2014 6:06:21 PM Subject: TCE scientific review

On the Mountain View Commercial Owners call the other day there were questions about the body of research on TCE toxicological effects and in particular the developmental effects. The IRIS review is the most recent review to address this question that also went through several rounds of external scientific review before release in 2011. http://www.epa.gov/iris/supdocs/0199index.html.

During the IRIS file development, the National Research Council was asked to independently review and evaluate the scientific basis of TCE toxicity. That report was presented in 2006. http://www.nap.edu/catalog.php?record_id=11707

As for the developmental effects of TCE exposure, there are multiple reports that looked at exposures during pregnancy in animal models with both negative and positive reports. However, the often cited Johnson papers specifically sought to answer the threshold concentration associated with observed fetal heart malformations. Since this is precisely the question that the IRIS file is asking, these results are heavily referenced and used in the quantitative physiologically based pharmacokinetic model (PBPK model) used to reduce the uncertainty in translating the animal outcomes to the human population.

Both reviews also present epidemiologic studies, studies of human populations that may have been exposed to TCE. Typically, these studies do not supply specific dose or exposure concentrations as in the animal studies, however, they are very useful in suggesting if the outcome is observed in humans. Developmental effects were reported in several of these studies, the most often cited are Tucson, AZ, Milwaukee, WI and Endicott, NY. Additional health effects studies are currently underway for Camp Lejeune, NC and are projected to be released this year. Interestingly, the most common reported developmental heart defects observed in the animal studies are also the most frequent type of heart defects reported in the human studies. This adds additional plausibility to this effect being caused by TCE exposure.

I hope that the conclusions from both reviews, compiling the body of research on TCE toxicity, that the potential for fetal heart defects are both plausible and quantifiable and the inclusion of this significant effect in the evaluation of safe exposure levels are both prudent and health protective.

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